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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Minotti et al.

Serial No.: 09/954,953

Filed: September 18, 2001

Examiner:

Khare, Devesh

Group Art Unit: 1623

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For: METHOD FOR REDUCING
TOXICITY OF COMBINED
CHEMOTHERAPIES

Dated: August 30, 2002

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Commissioner for Patents
Washington, D.C. 20231-0001

INFORMATION DISCLOSURE STATEMENT

Sir:

In fulfillment of the requirements of candor and good faith set forth in 37 C.F.R. §1.56,
Applicant submits herewith the following Information Disclosure Statement in accordance with
the provisions of 37 C.F.R. §1.97 and 1.98.

1. U.S. PATENTS

US PATENT NO

TITLE

ISSUE DATE

4,203,900 to
Kaiser

Process for Preparing 2-Oxazolines

May 20, 1980

4,206,221 to
Miller et al.

Cephalomannine and Its Use in Treating Leukemic
Tumors

June 3, 1980

4,303,439 to
Howe et al.

2-Substituted 4-Alkyl or Trihaloalkyl-5-
Oxazolecarboxylic Acids as Safening Agents

December 1, 1981

Match & Return

09/05/2002 AOSMAN1 00000006 09954953
01 FC:126 180.00 DP

<u>US PATENT NO</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
4,354,029 to Kaiser et al.	Preparation of 2-Substituted-2-Oxazolines with Organic Zinc Salt Catalysts	October 12, 1982
4,360,678 to Howe et al.	2-Substituted-4-Alkyl or Trihaloalkyl-5- Diazolecarboxylic Acids	November 23, 1982
4,443,611 to Kaiser	Liquid Phase Preparation of 2-H-2-Oxazolines and 2-Substituted-2-Oxazolines	April 17, 1984
4,543,414 to Carson	Liquid Phase Preparation of 2-Substituted-2- Oxazolines with Cadmium Salt Catalysts	September 24, 1985
4,743,700 to Jamm et al.	Process for Fluorinating 1-Phenyl-2-Amino-1,3- Propanediol Compounds	May 10, 1988
4,814,470 to Colin et al.	Taxol Derivatives, Their Preparation and Pharmaceutical Compositions Containing Them	March 21, 1989
4,857,653 to Colin et al.	Process for the Preparation of Taxol and 10- Deacetyltaxol	August 15, 1989
4,876,399 to Holton et al.	Taxols, Their Preparation and Intermediates Thereof	October 24, 1989
4,877,881 to Bellotti et al.	Process of Preparing Pyrazoles, Isoxazoles and Analogues Thereof Having Activity as 5- Lipoxygenase Inhibitors	October 31, 1989
4,924,002 to Kostlan	Novel Process for the Preparation of Pyrazoles from Isoxazoles	May 8, 1990
4,924,011 to Denis et al.	Process for Preparing Taxol	May 8, 1990
4,924,012 to Colin et al.	Process for Preparing Derivatives of Baccatine III and of 10-Deacetyl Baccatine III	May 8, 1990
4,942,184 to Haugwitz et al.	Water Soluble, Antineoplastic Derivatives of Taxol	July 17, 1990
4,960,790 to Stella et al.	Derivatives of Taxol, Pharmaceutical Compositions Thereof and Methods for the Preparation Thereof	October 2, 1990
5,015,744 to Holton	Method for Preparation of Taxol Using an Oxazinone	May 14, 1991

<u>US PATENT NO</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
5,059,699 to Kingston et al.	Water Soluble Derivatives of Taxol	October 22, 1991
5,128,478 to Ito et al.	Oxazoline-Carboxylic Acid Derivatives and Method for the Preparation Thereof	July 7, 1992
5,136,060 to Holtan	Method for Preparation of Taxol Using an Oxazinone	August 4, 1992
5,194,635 to Kingston et al.	Rearranged Taxol Compounds and Method of Using in Testing of In Vivo Activity	March 16, 1993
5,208,237 to Hewawasam et al.	7-Oxypropylsulfonamido-Imidazo[4,5-B]Quinolin-2-Ones	May 4, 1993
5,227,400 to Holton et al.	Furyl and Thienyl Substituted Taxanes and Pharmaceutical Compositions Containing Them	July 13, 1993
5,243,045 to Holton et al.	Certain Alkoxy Substituted Taxanes and Pharmaceutical Compositions Containing Them	September 7, 1993
5,254,580 to Chen	7,8-Cyclopropataxens	October 19, 1993
5,264,591 to Bombardelli et al.	Baccatine III Derivatives	November 23, 1993
5,272,171 to Ueda et al.	Phosphonooxy and Carbonate Derivatives of Taxol	December 21, 1993
5,278,324 to Kingston et al.	Water Soluble Derivatives of Taxol	January 11, 1994
5,283,253 to Holton et al.	Furyl or Thienyl Carbonyl Substituted Taxanes and Pharmaceutical Compositions Containing Them	February 1, 1994
5,296,506 to Kingston	Rearranged Taxol Compounds and Method of Using in Testing of In Vivo Activity	March 22, 1994
5,319,112 to Kingston et al.	Method for the Conversion of Cephalomannine to Taxol and for the Preparation of N-Acyl Analogs of Taxol	June 7, 1994
5,352,806 to Gunawardana et al.	Taxol Derivatives	October 4, 1994

<u>US PATENT NO</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
5,399,726 to Holton et al.	Process for the Preparation of Baccatin III Analogs Bearing New C2 and C4 Functional Groups	March 21, 1995
5,420,337 to Patel et al.	Enzymatic Reduction Method for the Preparation of Compounds Useful for Preparing Taxanes	May 30, 1995
5,440,056 to Klein et al.	9-Deoxotaxane Compounds	August 8, 1995
5,449,790 to Zheng et al.	Preparation of 10-Deacetylbaccatin III and 7- Protected-10-Deacetylbaccatin III Derivatives from 10-Deacetyl Taxol A, 10-Deacetyl Taxol B, and 10- Deacetyl Taxol C	September 12, 1995
5,468,769 to Klein et al.	Paclitaxel Derivatives	November 21, 1995
5,476,954 to Bourzat et al.	Process for Preparing Taxane Derivatives, New Derivatives Obtained and Pharmaceutical Compositions Containing Them	December 19, 1995
5,556,878 to Kelly et al.	$\Delta^{6,7}$ -Taxols Antineoplastic Use and Pharmaceutical Compositions Containing Them	September 17, 1996
5,580,997 to Bouchard et al.	Baccatin III Derivatives	December 3, 1996
5,589,502 to Tsujihara et al.	Baccatin Derivatives and Processes for Preparing the Same	December 31, 1996
5,616,739 to Mas et al.	Method of Preparing Taxane Derivatives	April 1, 1997
5,618,952 to Holton et al.	Synthetic Process for the Preparation of Tricyclic and Tetracyclic Taxanes	April 8, 1997
5,621,121 to Cammercon et al.	Process for the Preparation of Taxane Derivatives	April 15, 1997
5,635,531 to Chen	3'-Aminocarbonyloxy Paclitaxels	June 3, 1997
5,637,732 to Holton et al.	Tricyclic and Tetracyclic Taxanes	June 10, 1997

<u>US PATENT NO</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
5,646,176 to Golik et al.	Phosphonooxymethyl Ethers of Taxane Derivatives	July 8, 1997
5,670,658 to Bastart	Process for Preparing 7-Trialkylsilyl Baccatin III	September 23, 1997
5,677,470 to Tsujihara et al.	Baccatin Derivatives and Processes for Preparing the Same	October 14, 1997
5,710,287 to Holton et al.	Taxanes Having and Amino Substituted Side-Chain and Pharmaceutical Compositions Containing Them	January 20, 1998
5,721,268 to Holton et al.	C7 Taxane Derivatives and Pharmaceutical Compositions Containing Them	February 24, 1998
5,728,687 to Bissery	Antitumour Compositions Containing Taxane Derivatives	March 17, 1998
5,728,725 to Holton et al.	C2 Taxane Derivatives and Pharmaceutical Compositions Containing Them	March 17, 1998
5,760,252 to Holton et al.	Synthetic Process for the Preparation of Tricyclic and Tetracyclic Taxanes	June 2, 1998
5,767,296 to Terasawa et al.	Deacetoxytaxol Derivatives	June 16, 1998
5,773,461 to Wittma et al.	7-Deoxy-6-Substituted Paclitaxels	June 30, 1998
5,808,102 to Poss et al.	Phosphorus Bearing Taxanes Intermediates	September 15, 1998
5,840,931 to Bouchard et al.	Taxoids, Their Preparation and Pharmaceutical Compositions Containing Them	November 24, 1998
5,847,170 to Bouchard et al.	Taxoids, Their Preparation and Pharmaceutical Compositions Containing Them	December 8, 1998
5,908,835 to Bissery	Anti-Tumor Compositions Containing Taxane Derivatives	June 1, 1999
6,005,120 to Holton et al.	Tricyclic and Tetracyclic Taxanes	December 21, 1999

<u>US PATENT NO</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
6,020,507 to Gibson	Synthesis of Paclitaxel from Baccatin III by Protection of the 7-Hydroxyl of Baccatin III Using a Strong Base and an Electrophile	February 1, 2000
6,043,375 to Bourzat et al.	Process for the Preparation of an Oxazolidinecarboxylic Acid Which is Useful for Preparing Therapeutically Active Taxoids	March 28, 2000
6,072,060 to Suidell et al.	Synthesis of Taxol, Taxol analogs and Their Intermediates with Variable A-Ring Side Chain Structures and Compositions Thereof	June 6, 2000
6,096,909 to Ojima	Taxoid Anti-Tumor Agents and Pharmaceutical Compositions Thereof	August 1, 2000
6,100,411 to Ojima	Taxoid Anti-Tumor Agents and Pharmaceutical Compositions Thereof	August 8, 2000
6,214,863 B1 to Bissery	Antitumor Compositions Containing Taxane Derivatives	April 10, 2001
6,239,167 B1 to Bissery	Antitumor Compositions Containing Taxane Derivatives	May 29, 2001

FOREIGN PATENT DOCUMENTS

<u>PUBLICATION NO.</u>	<u>PUBLICATION DATE</u>	<u>COUNTRY</u>
JP 55-145650	11/13/80	Japan
JP 61-005022	01/10/86	Japan
JP 61-51578	11/10/86	Japan
JP 60-222416	11/07/85	Japan
JP 61-115022	06/02/86	Japan
JP 9208572A	08/12/97	Japan
WO 90/02738	03/22/90	PCT
WO 92/09589	06/11/92	PCT
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WO 96/14309	05/17/96	PCT
WO 96/23779	08/08/96	PCT
WO 97/09979	03/20/97	PCT

PUBLICATION NO.	PUBLICATION DATE	COUNTRY
WO 97/23472	07/03/97	PCT
WO 97/32578	09/12/97	PCT
WO 97/32869	09/12/97	PCT
WO 98/01435	01/15/98	PCT
WO 98/22451	05/28/98	PCT
WO 99/33462	07/08/99	PCT
EP 0 359 516 B1	08/10/94	EPO
EP 0 400 971 B1 & A3	07/29/98	EPO
EP 0 428 376 B1	01/10/96	EPO
EP 0 505 047 B1 & A1	04/24/96	EPO
EP 0 537 905 B1 & A1	03/06/96	EPO
1,061,330	08/28/79	Canada
1,695,918	05/06/71	German
2,919,891	12/04/80	German

Copies of each of these references are attached herewith. All of the references listed above are also listed on Applicant's Substitute Form PTO-1449 which is attached to this Information Disclosure Statement for the convenience of the Examiner.

As this Information Disclosure Statement is being mailed after receipt of the first Office Action on the merits, but before a Final Rejection, it is believed to be timely with the required fee of \$180.00, which is submitted herewith. Please charge any deficiencies or credit any overpayment to Deposit Account No. 08-2461.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,

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